Results were similar in the ITT population (HER2+ or HER2- patients). CONCLUSIONS: Utility values for patients with HER2+ MBC are generally similar for patients receiving letrozole plus lapatinib or letrozole plus placebo. Post-progression utility values were based largely on a single assessment for each patient and are may not be representative of patient utility during all post-progression survival.

PCN106

IMPACT OF AN INDIVIDUAL'S LOCUS OF CONTROL ON UTILITY VALUES FOR HEAD AND NECK CANCER HEALTH STATES

Levy AR[1], Szabo S[1], Johnston K[1], Dobson RL[1], Donato BM[2]
[1]Oxford Outcomes Ltd, Vancouver, BC, Canada, [2]Bristol-Myers Squibb Co, Wallingford, CT, USA

OBJECTIVES: The determinants of utilities for health are largely unknown. The psychosocial construct *Locus of control* (LOC) describes the extent to which individuals feel their health is determined by their actions, by a powerful external figure, or by chance. LOC is associated with health-related quality of life among cancer patients but its impact on utilities has not been examined. The objective was to estimate the effect of LOC on utilities for head and neck cancer (HNC) health states among Canadians without cancer. **METHODS:** A convenience sample of respondents without cancer was recruited according to the age- and sex-distribution of Canada in Vancouver and Toronto. Standard gamble utilities were elicited for health states describing HNC stage and type. Standardized health state descriptions were based on literature review, trial data, and feedback from clinicians experienced in HNC treatment and quality-of-life researchers. Respondents completed the validated Multidimensional Health LOC scale. Mixed regression models were used to determine associations between interval locus of control scores and utilities, adjusting for demographic variables, HNC stage and type. **RESULTS:** Utility values were elicited from 101 respondents with a mean age of 47 years (48% male). Mean utilities were: 0.62 for locoregional laryngeal, 0.61 for locoregional non-laryngeal, 0.57 for recurrent non-laryngeal, 0.56 for recurrent laryngeal, 0.52 for metastatic non-laryngeal, 0.50 for metastatic laryngeal, and 0.34 for post-progression, HNC. There was suggestive evidence that LOC was associated with utilities ($P = 0.079$). Respondents who had a dominant *Chance* LOC rated health states significant lower ($P = 0.012$): for every one unit increase on the *Chance* subscale, there was a decrement of 0.011 in mean utility value. **CONCLUSIONS:** This evidence indicates that LOC is a determinant of utilities for head and neck cancer health states. Replicating these findings in other populations and diseases would shed insight into the psychosocial determinants of preferences.

PCN107

EVALUATION OF QUALITY OF LIFE FOR ANTI-CANCER TREATMENT AMONGST KOREAN METASTATIC BREAST CANCER PATIENTS: A MULTICENTER, CROSS-SECTIONAL STUDY

Lee JY[1], Ko SK[1], Kim EJ[2]
[1]Pfizer Pharmaceuticals Korea Limited, Seoul, South Korea, [2]Graduate School of Public Health, Seoul National University, Seoul, South Korea

OBJECTIVES: This research is designed to reveal Quality of life of Korean patients with metastatic breast cancer for cancer treatments. **METHODS:** This is a multicenter, cross-sectional study in breast cancer patients receiving palliative chemotherapy. Total 199 patients with metastatic breast cancer were interviewed from 4 centers. Clinical, socio-demographic, and quality of life data were collected. Subjects completed a face-to-face interview with trained interviewer to assess their health status for breast cancer treatment. Patients recalled the before diagnosis status under current situation. we used the three methods to evaluate the health status; EORTC QLQ-C30, BR-23, EQ-5D. **RESULTS:** Overall utility weights for EORTC QLQ C30 and EQ-5D was 0.81 and 0.78 respectively(before diagnosis). It is higher than those of current (EORTC QLQ-C30: 0.54, EQ-5D: 0.60). the patients who are before diagnosis estimated higher functioning score compared to current. (physical functioning scale; before cancer: 92.8, current 65.3) The higher the score is, the better patients' function is. Symptom scale scores are the similar with functioning scale scores. The higher the score is, the worse the symptom is. before cancer status has lower symptom scale scores than current. (fatigue symptom scale; Before cancer: 25.2, current: 48.5) BR 23 scale, there were deteriorations in patients for all domains compared to scores of before cancer patients. Especially, patient' current body image score is significantly lower than that of before diagnosis patients. (before diagnosis: 91.4, current: 46.4) **CONCLUSIONS:** There are few study of Quality of life in breast cancer patients. It is meaningful that this study provided the utility weights for breast cancer patients in Korea.

PCN108

PSYCHOMETRIC VALIDATION OF A PATIENT QUESTIONNAIRE EVALUATING SATISFACTION WITH A DARBEPOETIN ALPHA PRE-FILLED DEVICE FOR SELF-INJECTION (ARANESP®SURECLICK™DEVICE), AND A HOME-SERVICE (2CARE®SERVICE) IN CHEMOTHERAPY-INDUCED ANAEMIC CANCER PATIENTS

de Jong FA[1], Viala-Danten M[2], van Herwaarden RH[1], Poppe KA[1], van Haaster CM[1], Meunier J[2], Rijnierse JJ[1]
[1]Amgen BV, Breda, The Netherlands, [2]Mapi Values, Lyon, France

OBJECTIVES: To validate a questionnaire evaluating patient satisfaction with the darbepoetin alpha pre-filled device for self-injection (Aranesp®SureClick™device) and the 2care®service for product delivery and helping patients with injection at home. **METHODS:** Patients with non-myeloid malignancies to be treated with 500mcg darbepoetin alfa three-weekly for chemotherapy-induced anaemia using the Aranesp®SureClick™device and 2care®service were enrolled in a prospective, observational study in the The Netherlands. Following each of the first three darbepoetin alpha-injections, patients completed a questionnaire specifically developed for this study. This questionnaire included items (answer ranges, 0–10) related to satisfaction with the device (5 items: ease-of-use/pain /anxiety/expectations/overall-satisfaction) and the 2care®service (9 items: quickness/delivery/punctuality/friendliness/competency/flexibility/information/usefulness/overall-satisfaction). Questionnaire structure was defined using factor analyses and confirmed by multi-trait analysis. Internal consistency was evaluated by Cronbach's alfa. Ranges of minimal important differences (MIDs) were calculated using anchor-based and distribution-based methods. Determinants of overall satisfaction with the Aranesp®SureClick™device were analyzed by multiple regression analyses. RESULTS: A total of 283 patients were evaluable. At first injection, median item-scores ranged from 8.0–9.4. Two composite scores were defined (1 item not correlated with any scores: quickness 2care®-contact making appointment): *satisfaction with the Aranesp®SureClick™device* and *satisfaction with the 2care®service*. Item-score correlations ranged from 0.61–0.81 and 0.64–0.79, respectively. Cronbach's alfas were 0.85 and 0.84. All items met convergent and discriminant validity criteria. Plausible MIDs were 0.5–0.7 and 0.3 for satisfaction with the Aranesp®SureClick™device and 2care®service, respectively. At first injection, satisfaction with the Aranesp®SureClick™device was mainly determined by expectations, pain, and ease-of-use. After 3 injections, the main driver was ease-of-use. **CONCLUSIONS:** Patients were satisfied with the Aranesp®SureClick™device and 2care®service. The satisfaction questionnaire showed good dimension structure and internal consistency reliability. MIDs were provided for interpretation of scores. Determinants of patient satisfaction were shown to change (ease-of-use becoming the main driver, while pain importance decreased) while the patient accumulates experience with the Aranesp®SureClick™device.

PCN109

DEVELOPMENT OF THE PATIENT-REPORTED VERSION OF THE COMMON TERMINOLOGY CRITERIA FOR ADVERSE EVENTS (PRO-CTCAE)

Basch E[1], Reeve B[2], Cleeland C[3], Sloan J[4], Mendoza T[3], Abernethy A[5], Bruner D[6], Hay J[1], Atkinson T[1], Sit L[1], Minasian L[2], O'Mara A[2], Burke L[7], Schrag D[8]
[1]Memorial Sloan-Kettering Cancer Center, New York, NY, USA, [2]National Cancer Institute, Bethesda, MD, USA, [3]U.T.M.D. Anderson Cancer Center, Houston, TX, USA, [4]Mayo Clinic, Rochester, MN, USA, [5]Duke University, Durham, NC, USA, [6]University of Pennsylvania, Philadelphia, PA, USA, [7]Food and Drug Administration, Silver Spring, MD, USA, [8]Dana-Farber Cancer Institute, Boston, MA, USA

OBJECTIVES: The standard lexicon for reporting adverse events in NCI-sponsored trials is the Common Terminology Criteria for Adverse Events (CTCAE), which consists of over 800 individual items. Currently, all items are reported by clinicians. However, multiple studies have found that clinicians tend to underreport symptom severity and onset compared with patient self-reports. In October 2008, the NCI contracted a multi-institution consortium to develop patient versions of CTCAE items, and an administration electronic platform. **METHODS:** A multidisciplinary committee systematically identified CTCAE items with sufficient subjective component to be amenable to patient reporting. Systematic reviews of publications and existing questionnaires, and analyses of existing data sets were conducted to determine optimal formats for questions and response options, and plain-language terms for each new "PRO-CTCAE" item. Cognitive interviews were conducted in 100 patients to refine items. **RESULTS:** Seventy-seven "symptoms" were identified in the CTCAE which were amenable to patient reporting. The committee determined that measured attributes for each symptom should include frequency, severity, and activity interference, assessed via discrete questions for each symptom. A standardized format for questions and response options, and plain language terms for each symptom were formulated. A web-based platform was developed for creating and administering the new PRO-CTCAE items. **CONCLUSIONS:** A patient version of the CTCAE system, known as the PRO-CTCAE, has been developed. This prototype is undergoing further testing to assess its validity, reliability, usability, and feasibility for use in a variety of cancer care settings. The PRO-CTCAE system both will enhance adverse event reporting by directly integrating patient experiences and will foster consistency of data collection methods across studies.

PCN110

HOW MUCH DO PATIENTS WITH RENAL CELL CARCINOMA (RCC) VALUE PROGRESSION FREE SURVIVAL IN MEDICAL DECISION MAKING?—RESULTS FROM A BENEFIT-RISK CONJOINT STUDY

Hauber AB[1], Mohamed AF[1], Johnson FR[1], Neary MP[2]
[1]RTI Health Solutions, Research Triangle Park, NC, USA, [2]Novartis Pharmaceuticals, Collegeville, PA, USA

BACKGROUND: Overall survival (OS) has been traditionally used as the primary endpoint in oncology trials, however cross-over to 2nd line agents may result in biases for OS. Recent trials have used progression free survival (PFS) as the primary endpoint. Understanding patient preferences regarding expected PFS vs. avoidance of risk for toxicities in medical decision-making is needed. **OBJECTIVES:** To estimate RCC patients' willingness to accept toxicities and medication-related risks to increase PFS. **METHODS:** US residents aged 18 years and over with RCC completed a web-enabled, choice-format conjoint survey that presented a series of 12 trade-off questions, each including a pair of hypothetical RCC medication profiles. Each profile was defined by efficacy (PFS), tolerability effects (fatigue, diarrhea, hand-foot syndrome, mouth

sores), and medication-related risks (liver failure, blood clot). OS was held constant at 32 months. Trade-off questions were based on predetermined experimental design with known statistical properties. Random-parameters logit model was used to estimate a preference weight for each attribute level. Preference weights were used to calculate maximum levels of risks patients were willing to accept for increases in PFS. **RESULTS:** A total of 138 US subjects completed the survey. PFS was the most important attribute to patients over the range of levels included in the survey, while remaining attributes were ranked in order of importance as: fatigue, diarrhea, liver failure, hand-foot syndrome, blood clot, mouth sores. Increasing PFS by 10 months was as important as avoiding severe fatigue and 2-times as important as avoiding severe mouth sores. Patients were willing to accept blood-clot risks up to 5.5% (95% CI: 3.6%–8.6%) and liver-failure risks up to 3.6% (95% CI: 2.6%–4.8%) to increase PFS by 10 months. **CONCLUSIONS:** PFS is a clinical outcome that is important to RCC patients. Patients were willing to accept higher treatment-related risks to increase PFS.

PCN111

PRO LABELLING CLAIMS IN ANTINEOPLASTIC AGENTS

Caron M, Emery MP
MAPI Research Trust, Lyon, France

OBJECTIVES: To review PRO labelling claims achieved in antineoplastic products in Europe and in the US. METHODS: PROLabels database was searched with neoplasm and oncology as keywords to identify antineoplastic agents with PRO labeling claims approved or revised in Europe since 1995 and in the US since 1998. FDA and EMEA websites and guidances were reviewed. Anti-emetic and analgesic products were not included. **RESULTS:** Among the 101 antineoplastic products approved, 18 were identified with PRO claims—10 in the U.S, 8 in Europe (including one in both agencies)—for 11 different indications: non-small cell lung carcinoma, prostatic neoplasms, small cell lung carcinoma, Kaposi sarcoma, chronic myeloid leukemia, astrocytoma, pleural malignant mesothelioma, breast neoplasms, head & neck neoplasms, stomach neoplasms and colorectal neoplasms. Survival was primary endpoint for 12 products. Other primary endpoints included time to progression, response rate and response duration. PROs included in labels were primary endpoints in only two cases: one product used in prostatic neoplasms (improvement in pain) and one product approved for pancreatic neoplasms (clinical benefit response including pain intensity, use of rescue medication and performance status). Both products were approved by the FDA. Health-related quality of life was clearly mentioned in the label of 7 products (4 approved by the EMEA including 2 approved after the publication of the EMEA and FDA guidances, and 3 by the FDA, all approved before the publication of the guidances). Of these 7 products, 3 approved by the EMEA and 1 by the FDA had an indication for non-small cell lung carcinoma. **CONCLUSIONS:** PROs are rarely used as primary endpoints in approval of antineoplastic agents except for assessing palliative response. When assessed, health-related quality of life is used as a supportive endpoint, and more often associated with non-small cell lung carcinoma, especially in Europe.

PCN112

LITERATURE REVIEW AND PRODUCT LABEL CLAIM REVIEW FOR THE DEVELOPMENT OF A PATIENT-REPORTED OUTCOME RESEARCH STRATEGY FOR CANCER-RELATED ANEMIA

Hackshaw MD, Brown J
Eli Lilly and Company, Indianapolis, IN, USA

OBJECTIVES: An appraisal of patient-reported outcome (PRO) endpoints and existing instruments to measure such endpoints was conducted to identify and critically review potentially relevant and appropriate instruments for use in clinical trials of cancer-related anemia (CRA). The purpose of the study was to determine what PRO endpoints and instruments have been used to assess the impact of treatment in reducing CRA symptoms, and whether the instruments identified were likely to be of the standard acceptable by regulatory authorities to support a label claim. **METHODS:** A systematic search and review of 1486 published scientific abstracts was conducted using MEDLINE and EMBASE, as well as the supporting statements in regulatory agency labels for drugs used in the treatment of anemia. Consistency of the identified PRO measures and their psychometric properties with the current Food and Drug Administration (FDA) draft guidance on PROs supporting a labeling claim was also evaluated. **RESULTS:** A total of 29 instruments were identified. Four instruments were found to support a label claim or used specifically in the CRA population (FACT-F, FACT-An, CLAS/LASA, EORTC QLQ-C30); these were assessed further. Twenty-five were excluded from further assessment because they were specific to a particular disease other than cancer and covered aspects specific to these diseases which were not relevant to the CRA population. Other exclusion reasons included measurement of general health or health-related quality of life (HRQOL) and other symptoms that were neither specific to cancer nor anemia. **CONCLUSIONS:** None of the four instruments assessed were found to meet all the criteria in the FDA draft guidance; however, the findings help inform the design of new PRO instruments for CRA.

PCN113

HEALTH RELATED QUALITY OF LIFE, FEAR OF RECURRENCE, IMPACT OF EVENTS, ILLNESS INTRUSIVENESS AND PSYHOLOGICAL DISTRESS IN NON-MUSCLE INVASIVE BLADDER CANCER PATIENTS

Sansgiry S[1], Lerner SP[2], Amiel GE[2], Mei M[1], Latini DM[1]
[1]Baylor College of Medicine; Health Services Research & Development Center of Excellence, Michael E. DeBakey VA Medical Center, Houston, TX, USA, [2]Baylor College of Medicine, Houston, TX, USA

OBJECTIVES: The purpose of this study was to explore differences among Veterans and private-patients on health related quality of life (HRQOL), fear of recurrence (FOR), impact of events (IE), illness intrusiveness (IITF) and psychological distress in non-muscle invasive bladder cancer (NMIBC) patients and provide direction for further study. **METHODS:** Cross sectional study design was used. Participants were drawn from a large private hospital (N = 38) and Veterans Affairs hospital (N = 29) in the southeast United States. HRQOL was measured with EORTC-QLQ-C30. FOR was measured with 5-item measure used in the Cancer of the Prostate Strategic Research Endeavor study. The IE Scale measures subjective response to stress and consists of two subscales, intrusive thoughts and avoidance. The IITF measure assesses impact of illness on functioning and consists of three subscales, intimacy, instrumental life and relationship-personal development. Psychological distress was measured with the Brief Symptom Index (BSI), an 18-item measure. Differences among Veterans vs. private-patients were assessed with student t-test or chi-square as appropriate. Analyses were performed using the SAS v9.1.3. **RESULTS:** Majority of respondents were older (mean age at diagnosis 65.4(± 8.8) years), white (91.1%), males (83.6%), married (70.2%) and largest percentage (35.8%) reported getting some college education. Veterans group did not differ from private-patients on age, education, ethnicity, relationship status, number of bladder cancer treatments received or time since diagnosis (years) ($p > 0.05$), but differed significantly on gender ($p = 0.0016$). Number of comorbidities were also higher in the Veterans group ($p = 0.0214$). Veterans indicated significantly higher FOR, psychological distress, illness intrusiveness on intimacy and instrumental life, and lower HRQOL compared to private-patients ($p < 0.05$). **CONCLUSIONS:** Veterans had higher level of FOR and psychological distress but lower HRQOL, than private-patients. Interventions to manage patients' fear of recurrence, psychological distress and help them adapt to altered routine may assist NMIBC patients.

PCN114

EXPLORING THE BURDEN OF ILLNESS ON NEWLY DIAGNOSED ESOPHAGEAL CANCER PATIENTS IN TAIWAN –PRELIMINARY ANALYSIS

Lin HW, Ku CH, Lee RF, Shih TP, Liu YY, Lin CY
China Medical University, Taichung, Taiwan

OBJECTIVES: Esophageal cancer (EC) is the seventh cancer among male patients in Taiwan. Difficulty swallowing makes EC patients vulnerable to nutritional challenges and impacts their treatment outcomes and well-being. The aims of this study are to explore the EC patients' burden of illness on nutritional and well-being aspects. **METHODS:** A longitudinal observation study is conducting to recruit newly diagnosed EC patients from the CMU Hospital in Taichung, Taiwan since June 2009. Fresh EC patients were assessed before (T0) and after receiving any main treatments (T1 [1-month], T2 [3-month], T3 [6-month] after treatment(s)) if it is not impossible. Well trained interviewers solicited patients' responses on 1) Nutritional Risk Screen (NRS-2002); 2) Chinese versions of EQ-5D and FACT-E. The descriptive analyses were performed to examine the trends among different stages of EC patients. **RESULTS:** Up to the date of analysis(December 31, 2009), of 27 recruited EC patients, average age was 53 ± 9 years-old and more than 90% were diagnosed with squamous cell carcinoma (³85% with clinical stage at III and above). There were 23, 14, 5 and 2 patients completed the T0, T1, T2 and T3 assessments, respectively. Approximately 70% and 80% of patients at T0 and T2 had NR-2002S scored greater than 3 (with defined risk of malnutrition). From T0 to T3, upon the solicited, completed responses, patients seemed to be deteriorated on the daily activities and social well-being (i.e., self-care, usual activity of EQ-5D, and physical and social well-being of FACT-E) but improve on esophageal cancer related symptoms and signs (additional concerns of EC) after treatments. **CONCLUSIONS:** This preliminary analysis showed the extent of EC patients' burden of illness and its change over time. Further assessments are necessary to facilitate the decision making about appropriate management of EC patients on the aspect of nutrition and health-related quality of life.

PCN115

HEAD-TO-HEAD COMPARISONS OF QUALITY OF LIFE INSTRUMENTS FOR YOUNG ADULT SURVIVORS OF CHILDHOOD AND ADOLESCENT CANCER

Huang IC[1], Quinn G[2], Shenkman E[1], Shearer P[1]
[1]University of Florida, Gainesville, FL, USA, [2]H. Lee Moffitt Cancer Center and Research Institute, Tampa, FL, USA

OBJECTIVES: Although several health-related quality of life (HRQOL) instruments exist for adult cancer survivors, little attention has been paid to identify appropriate instruments for young adult survivors of childhood and adolescent cancer (YASCAC). We aim to make head-to-head comparisons of 3 HRQOL instruments for YASCAC. **METHODS:** We collected data via telephone interviews between 05/01/2009 and 09/30/2009 from 141 YASCAC who were off therapy at least 2 years without cancer and enrolled in the CSP and/or the UF Tumor Registry. Each subject reported his/her late effects (yes/no) and HRQOL. HRQOL was measured using the Quality of Life